Clinical Trials Sponsorship by Academic and Research Institutes: Challenges and Opportunities

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SPONSOR

The person/Organisation/Institution who takes on ultimate responsibility for the initiation, management, financing [or arranging the financing] of a clinical trial (ICH GCP).

AND

Responsibility to support the independent researcher to achieve rigorous research to international standards

Challenges in North-South collaborative research: Regulatory Oversight

- Multiple/Absent regulatory/ethics procedures
  - Large admin load/cost
  - Time reqd frequently underestimated

- Varying levels of regulatory “stringency” (WHO 2010) → risk of reduced protection

- Variable approval times for EC on average 5 mnths and 8-18mnths for National Authority approval (Geldenhuys et al., 2013)

Regulatory Oversight

- Level of risk not accommodated
- Focus often rest on procedural requirements and runs the risk of missing potential ethical issues.

Challenges: GCP/GCLP Burden of Duty

- GCP (WHO 1995, ICH 1996) and GCLP (WHO 2009) achieved with multiple highly skilled team members – stringent

- Variable level of awareness and financial/human resources to raise standards
  - Reality is small teams with extended roles.
  - Often limited, ad hoc training

- Site resources - often minimal equipment and unfunded core staff in trial units.

Challenges: GCP/GCLP

- Data Management
  - limited GCP compliant open access systems
  - unstable internet connections
  - limited trained staff necessary to develop/validate databases, and to check systems (data review)
  - One size wont fit all but a database of proven systems might harmonise practice better.

Challenges: Monitoring

- Extremely useful for early detection of training and resource needs:

BUT

- External monitoring is costly
- Extent of monitoring input required often lacks :
  - Contextual considerations
  - Risk evaluation

Commonly underfunded

Challenges: Clinical Trial Insurance

Insurance Cover

- Professional Indemnity (Registered Professional Cover) - Clinical negligence

  What level of cover is there ?

- No-fault Indemnity (Trial Related)
  - Sponsor provided – varies and relevance to international sites/participants often unknown
  - Shortage of companies
  - Lack of agreed models/good practices
  - Agreeing exclusions/excess payable

Summary

- Non-commercial sponsors deal with the challenges of academic research, plus additional context-related challenges
- Limited sponsor infrastructure often means either expensive outsourcing or gaps in the quality system
- Need for adapted approaches/tools for ensuring full protection of subjects/populations and compliance with research standards

Opportunity 1:Translating capacity development programme into practice

- Define need in EDCTP funded teams in Africa
- Sustainability
  - Retention of skilled staff
  - Career progression
  - Performance enhancement
- Establish a South-South exchange programme.

Opportunity 2: Develop a database of Clinical Trial Insurance

- Adequate and fair compensation to trial participants in case of harm (Helsinki,2013)
- Scope current contracts and companies providing indemnity
- Define key differences
- Identify potential risks
- Develop a model template for guidance with EDCTP appointed specialist

Opportunity 3: Define and agree internal and reciprocal monitoring systems

- Scope current systems/SOPs utilised by sponsors
- Draw up and agree guidelines for internal monitoring
- Draw up and agree guidelines for reciprocal monitoring between studies/sponsors
- Establish a training programme and training team

Opportunity 4: To share information on data management tools

- Scope current systems
- Identify good practices for different study designs
- Promote the exchange of information regarding off-line open access database systems

Opportunity 5: Donor - Sponsor relationship

- Helsinki (2013)
  - Access to intervention shown to be effective after the trial.
- Fill gaps in support from other granting bodies eg. staff salaries
- Establish sponsors in the South:
  - What are the core set of resources needed to assume the role?
  - Awareness raising and training

Running trials in resource poor settings is getting more complicated.

Non-commercial Sponsors should take every opportunity to work with EDCTP partners to continue to enable patient- and community-centered quality research of relevance in Africa

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THANK YOU